

ENDOCRINE DISRUPTORS: Interagency Announcement

Science to Achieve Results Program: 1999 Research Grants

Opening Date: June 19, 1998

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Introduction

This announcement is a collaborative effort between the Environmental Protection Agency, Department of the Interior, Department of Health and Human Services (National Institute of Environmental Health Sciences), and Department of Commerce (National Oceanic and Atmospheric Administration), and is endorsed by the Department of Agriculture, Department of Defense, Department of Energy, Centers for Disease Control and Prevention, Food and Drug Administration, and the Office of Science and Technology Policy. The purpose of this announcement is to develop a government-wide coordinated effort to stimulate innovative, multi-disciplinary research to address high priority scientific uncertainties related to the potential adverse effects of endocrine disrupting chemicals (EDC) in humans and wildlife.

Background

This research effort is an important mechanism for addressing priority national research needs identified by the Endocrine Disruptors Working Group (EDWG) of the Committee on Environment and Natural Resources, National Science and Technology Council. The Working Group recognized the need to promote collaboration between the Federal sector and academia and the private sector to ensure that scientific advances are timely and can be used to inform national policy on endocrine disruptors.

A number of overarching research needs were identified by the EDWG in the areas of human health, ecological effects, and exposure assessment as essential to the larger goal of determining the extent and magnitude of impact for endocrine disruptors on wildlife and human populations and to provide a firm scientific basis for a determination of the likely risk that EDCs pose to human health and the environment. Specifically, this research effort is designed to advance the following priority research needs:

- Establish relationships between exposure to EDCs and adverse outcomes for human diseases and impaired reproduction and development in vulnerable populations. Exposure during early critical life stages (fetal, neonatal, and childhood) are of special concern. Quantitation of EDC body burdens in vulnerable groups is needed, especially for non-persistent, non-chlorinated EDCs and chemical mixtures.
- Characterize interspecies variability among taxa and sensitive wildlife populations under field conditions. Increase emphasis on non-mammalian wildlife (e.g., amphibians, reptiles, birds, and invertebrates) that may be sensitive to endocrine disruption.
- Identify adverse outcomes (e.g., tumors and reduced fecundity) to

wildlife, to single individuals and to populations, as a result of EDC exposures.

Multiple Agency Interests

To address the increased need for research on endocrine disruptors, the following Federal organizations have combined their unique interests and missions into this coordinated research program. The following outlines specific agency interest in endocrine disruptors research:

Department of Agriculture (USDA).

The USDA seeks to minimize the presence of substances that could affect human health and safety, such as endocrine disruptors, in the environment and in the food supply.

Department of Commerce. National Oceanic and Atmospheric Administration (NOAA).

Endocrine disruptor research cuts across NOAA's strategic objectives of building sustainable fisheries, recovering protected species and promoting healthy coastal ecosystems. Understanding the impact of endocrine disruptors on the developmental and reproductive biology of marine and anadromous fish, marine mammals, sea turtles, and marine invertebrates is especially relevant.

Department of Defense (DoD), Tri-Service Toxicology Consortium [comprised of the Naval Medical Research Institute, Detachment (Toxicology); U.S. Army Medical Research Detachment; and the U.S. Air Force Toxicology Division] fosters preventive strategies for intervening with health risks from chemicals of military interest, including potential toxic insults to the endocrine, reproductive, neurological, and immune systems.

Department of Energy (DOE). The DOE funds research on endocrine disrupting chemicals as part of its effort to understand and reduce the environmental and public health threats from its facilities.

Environmental Protection Agency (EPA).

The objectives of the endocrine disruptor research program are to determine whether there are health effects occurring in human and wildlife populations and to improve understanding of endocrine disruptors in the environment. Chemicals that are known or suspected of being endocrine disruptors fall within the authorities and responsibilities of the EPA as mandated in 12 major environmental statutes to protect human health and the environment.

Department of Health and Human Services

Centers for Disease Control and Prevention. The human health consequences of endocrine disruptors are of concern as they relate to identification of human health hazards, surveillance of human diseases or exposures, determination of preventable risk factors for disease, and development and evaluation of prevention programs.

Food and Drug Administration.

Endocrine disruptors are of concern to FDA in its responsibilities for ensuring that foods are safe, wholesome, and honestly labeled, that medicines are safe and effective, and for regulating medical devices, cosmetics, veterinary drugs, and animal feed. Premarket review of substances, final product approval, and post-market surveillance establishes an additional need for information on endocrine disruptors.

National Institute of Environmental Health Sciences (NIH).

NIEHS supports research directed at characterizing human health impacts from exposure to environmental agents. Mechanistic research on chemicals which mimic or block the actions of natural hormones such as estrogens or androgens and epidemiologic studies of the health effects of EDCs in women, men, and children are high priorities. This research will provide a clearer picture of the exposure required for adverse health effects.

Department of the Interior (DOI).

The U.S. Geological Survey (USGS) and the U.S. Fish and Wildlife Service seek information on the ecological effects of endocrine disruptors in wild animals, including fish, amphibians, reptiles, birds, and mammals as a basis for decisions on the management and conservation of these biological resources.

Program Description

Research proposals are sought in the following areas:

1. Population-level effects of EDCs in wildlife

The goal of this component of the RFA is to solicit integrated, multi-disciplinary research on the ecological effects of EDCs. We are interested in studies that assess the impacts of EDCs at multiple levels of biological organization. Many studies have shown changes in endocrine homeostasis in terms of biochemical/histological measurements at the sub-organismal level, but the significance of these observations in terms of adverse effects on reproduction and development at the population-level is uncertain. Proposed studies may focus on understanding effects observed in the field or on

controlled studies in the laboratory or field; we encourage evaluation of empirical and/or theoretical linkages between endpoints at multiple levels of biological organization. Of continuing interest are those classes/groups of wild animals that are potentially at risk due to unique life history traits as they relate to reproductive strategies. There is no preference as to specific chemical stressors to study other than that they exert effects through mechanisms associated with endocrine function.

- Potential research could include either assessment of specific populations at sites known to be contaminated with suspected EDCs or evaluation of populations known to be adversely affected (e.g., animals in decline or those with a high percentage of individuals exhibiting abnormal pathologies) for reasons that may relate to EDCs. One approach might be to assess biological responses at the cellular and subcellular level that are suggestive of exposure to EDCs and relate these responses to adverse changes at the individual and population levels. This type of analysis would require a careful assessment of temporal considerations associated with exposure and effects. Relationship of responses across levels of biological organization could be evaluated using either empirical or conceptual models or a combination of the two.
- Research is needed which addresses prediction of the potential endocrine disrupting effects associated with the production and use of new chemicals on individuals and populations in terms of likely expression of toxicity. One approach might be to link controlled field or mesocosm studies to theoretical modeling that involves identification of the mechanism of action.

- Proposals are requested that focus upon relating endpoints suggestive of effects on endocrine function to adverse outcomes in individuals and populations. Most mechanistic endpoints indicative of alterations in specific endocrine systems cannot be easily linked to adverse biological effects. For example, there have been reports of the induction of vitellogenin in fish exposed to certain types of effluents, but the practical consequences of this estrogen-mediated response in terms of population viability are unclear (note, this is used solely as an example, not necessarily to solicit proposals on this specific topic to the exclusion of others). Because of the critical roles that successful reproduction and early development have on population dynamics, these endpoints are of particular interest. Animal models for this research are not constrained to any particular class/species but, to the extent practically possible, should focus on species/classes that are ecologically important but that have not traditionally been the focus of research in this area. Of particular interest are species which might be at significant risk due either to unique aspects of life history and/or potential EDC exposure. This might include oviparous animals, long-lived animals with limited reproductive capacity, invertebrates, or amphibians.

2. Effects of exposure to EDCs during development on human health

The goal of this component of the RFA is to encourage integrated, multi disciplinary epidemiologic, toxicologic, and basic science research on the effects of EDCs on human health. Research is sought to determine the health consequences from **exposures during in utero, neonatal, and/or childhood development** to agents that

interfere with function of the endocrine system. Health endpoints of interest may be manifest before birth, during the neonatal period, during childhood, puberty, and in adulthood. New methods to characterize human exposure during these critical windows of development are encouraged.

Health consequences should be considered in humans and animal models in males and females. Conditions of interest in males include birth defects, including hypospadias and other urogenital abnormalities; alterations in the normal growth and development of male sex organs, including prostate and testes; puberty; changes in male hormone patterns; and sperm count and quality. In females, health endpoints include birth defects; onset of menarche and other aspects of pubertal development; menstrual disturbances and alterations in hormone patterns; and female infertility, including endometriosis. Studies of potential EDC impact on physical and mental growth and development are appropriate in both genders.

- Proposals are requested that focus on the development of animal models of endocrine disruptor-induced human diseases, with special attention on determining modes and mechanisms of action for use in low dose extrapolation of effects on reproductive development. Studies that integrate physiologically-based pharmacokinetic models of chemical metabolism and distribution with biologically-based quantitative dose-response modeling components are of special interest. Laboratory studies can include whole animal effects and tissue and cell culture studies of cellular and molecular effects of exposure.
- Epidemiologic studies of the health consequences of EDCs are encouraged. Improved methods of exposure assessment for individual

chemicals or environmentally relevant mixtures is a critical element of all epidemiologic studies in this field. Case control, cohort, and other novel study designs are encouraged. The development of new analytical techniques and biomarkers to measure EDCs currently in commercial use but that may not be as persistent in the environment as the organochlorines is needed. Examples of classes of EDCs not well studied to date include fungicides, herbicides, and industrial chemicals such as bisphenol A, alkyl phenols, and phthalates.

- Exposure assessment studies to describe the levels of EDC chemicals currently or recently in use and in the environment are encouraged. These studies should seek to relate past and current environmental levels of exposure with human body burden and health outcomes. The development of methods from which to extrapolate between environmental levels and human exposures is encouraged.

In all cases, we welcome and encourage the submission of proposals from groups of investigators and institutions that can bring sufficient multi-disciplinary expertise to address the outlined areas.

Background information regarding the state-of-the-science can be obtained by consulting Kavlock et al, 1996¹, Ankley, et al, 1997², Crisp et al 1998³ and the EPA Research Strategy on Endocrine Disruptors. The latter document is available on the Internet (<http://www.epa.gov/ORD/resplans/resplans.html>). These documents are meant to provide background information, not specific research priorities for this RFA.

Funds Available

Approximately \$8-10M will be available to support this program from the participating Agencies and Departments during the first year. The upper limit for awards is \$500,000 per year, total costs. Awards up to three years may be requested and are subject to the availability of funds.

¹Kavlock, R.J., G.P. Daston, C. DeRosa, P. Fenner-Crisp, L.E. Gray, S. Kaattari, G. Lucier, M. Luster, M.J. Mac, C. Maczka, R. Miller, J. Moore, R. Rolland, G. Scott, D.M. Sheehan, T. Sinks, and H.A. Tilson (1996). *Research needs for the risk assessment of health and environmental effects of endocrine disruptors: a report of the US EPA sponsored workshop*. Environ. Health Perspectives 104 (Supplement 4):715-740.

²Ankley, G.T., R.D. Johnson, N.E. Detenbeck, S.P. Bradbury, G. Toth, and L. Folmar, 1997. *Development of a research strategy for assessing the ecological risk of endocrine disruptors*. Rev. Toxicol. 1:71-106.

³Crisp, T.M., E.D. Clegg, R.L. Cooper, W.P. Wood, D.G. Anderson, K.P. Baetcke, J.L. Hoffmann, M.S. Morrow, D.J. Rodier, J.E. Schaeffer, L.W. Touart, M.G. Zeeman, Y.M. Patel (1998). *Environmental endocrine disruption: an effects assessment and analysis*. Environ. Health Perspectives 106 (Supplement 1):11-56.

Healthy People 2000

The cooperating agencies are committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA on endocrine disruption is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (full report: stock number 017-001-00474-0 or summary report: stock number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-512-1800).

Eligibility Requirements

Academic and not-for-profit organizations located in the U.S., and state or local governments, are eligible under all existing authorizations. Profit-making firms are not eligible to receive grants under this program. Federal Laboratories, national laboratories funded by federal agencies (FFRDCs), and federal employees are not eligible to apply to this program. Federal employees are encouraged to cooperate or collaborate with academic and not-for-profit organizations within the limits imposed by applicable legislation and regulations. Potential applicants who are uncertain of their eligibility should contact Dr. Robert E. Menzer (listed under "Contacts").

Standard Instructions for Submitting an Application

This section contains a set of special instructions related to how applicants should apply for a research grant under this solicitation. Proposed projects must be for research designed to advance the state of knowledge in the research areas described in this solicitation.

Sorting Codes

In order to facilitate proper assignment and review of applications, each applicant is asked to identify the topic area in which the application is to be considered. At various places within the application, applicants will be asked to identify this topic area by using the Sorting Code. The Sorting Code for this solicitation is

99-NCERQA-D1 for *Population-level effects of EDCs in wildlife*

99-NCERQA-D2 for *Effects of exposure to EDCs during development on human health*

The Sorting Code must be placed at the top of the abstract (as shown in the abstract format), in Box 10 of Standard Form 424 (as described in the section on SF424), and should also be included in the address on the package that is sent to EPA (see the section on how to apply).

The Application

The initial application is made through the submission of the materials described below. **It is essential that the application contain all the information requested and be submitted in the formats described.** If it is not, the application may be rejected on administrative grounds. If an application is considered for award, (i.e., after external peer review and internal review) additional forms and other information will be requested by the Project Officer of the funding agency. **The application should not be bound or stapled in any way.** The Application contains the following:

- A. Standard Form 424:** The applicant must complete Standard Form 424 (see attached form and instructions). This form will act as a cover sheet for the application and **should be its first page.** Instructions for completion of the SF424 are included with the form. The form must contain the original signature of an authorized representative of the applying institution. Please note that both the Principal Investigator and an administrative contact should be identified in Section 5 of the SF424.
- B. Key Contacts:** The applicant must complete the Key Contacts Form (attached) as the second page of the submitted application.
- C. Abstract:** The abstract is a very important document. Prior to attending the peer review panel meetings, some of the panelists may read only the abstract. Therefore, it is critical that the abstract accurately describe the research being proposed and convey all the essential elements of the research. Also, in the event of an award, the abstracts will form the basis for an Annual Report of awards made under this program.

The abstract should include the following information, as indicated in the example format provided:

- 1. Sorting Code:** Use the code 99-NCERQA-D1 or 99-NCERQA-D2.
- 2. Title:** Use the exact title as it appears in the rest of the application.
- 3. Investigators:** List the names and affiliations of each investigator who will significantly contribute to the project. Start with the Principal Investigator.
- 4. Project Summary:** This should summarize: (a) the **objectives** of the study (including any hypotheses that will be tested), (b) the experimental **approach** to be used (which should give an accurate description of the project as described in the proposal), (c) the **expected results** of the project and how it addresses the research needs identified in the solicitation, and (d) the estimated **improvement in risk assessment or risk management** that will result from successful completion of the work proposed.
- 5. Supplemental Keywords:** A list of suggested keywords is provided for your use. Do not duplicate terms already used in the text of the abstract.
- D. Project Description:** This description must not exceed fifteen (15) consecutively numbered (center bottom), 8.5x11-inch pages of single-spaced standard 12-point type with 1-inch margins. The description must provide the following information:
 - 1. Objectives:** List the objectives of the proposed research and the hypotheses being tested during the project and briefly state why the intended research is important. This section can also include any

background or introductory information that would help explain the objectives of the study (one to two pages recommended).

2. Approach: Outline the methods, approaches, and techniques that you intend to employ in meeting the objective stated above (five to 10 pages recommended).

3. Expected Results or Benefits: Describe the results you expect to achieve during the project, the benefits of success as they relate to the topic under which the proposal was submitted, and the potential recipients of these benefits. This section should also discuss the utility of the research project proposed for addressing the environmental problems described in the solicitation (one to two pages recommended).

4. General Project Information: Discuss other information relevant to the potential success of the project. This should include facilities, personnel, project schedules, proposed management, interactions with other institutions, etc. (one to two pages recommended).

5. Important Attachments: Appendices and/or other information may be included but must remain within the 15-page limit. References cited are in addition to the 15 pages.

E. Resumes: The resumes of all principal investigators and important co-workers should be presented. Resumes must not exceed two consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced standard 12-point type with 1-inch margins for each individual.

F. Current and Pending Support: The applicant must identify any current and pending financial

resources that are intended to support research related to that included in the proposal or which would consume the time of principal investigators. This should be done by completing the appropriate form (see attachment) for each investigator and other senior personnel involved in the proposal. Failure to provide this information may delay consideration of your proposal.

G. Budget: The applicant must present a detailed, itemized budget for the entire project. This budget must be in the format provided in the example (see attachment) and not exceed two consecutively numbered (bottom center), 8.5x11-inch pages with 1-inch margins. Please note that institutional cost sharing is not required and, therefore, does not have to be included in the budget table. If desired, a brief statement concerning cost sharing can be added to the budget justification.

H. Budget Justification: This section should describe the basis for calculating the *personnel*, *fringe benefits*, *travel*, *equipment*, *supplies*, *contractual support*, and *other* costs identified in the itemized budget and explain the basis for their calculation (special attention should be given to explaining the *travel*, *equipment*, and *other* categories). This should also include an explanation of how the indirect costs were calculated. This justification should not exceed two consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced standard 12-point type with 1-inch margins.

I. Quality Assurance Narrative Statement: For any project involving data collection or processing, conducting surveys, environmental measurements, and/or modeling, provide a statement

on how quality processes or products will be assured. This statement should not exceed two consecutively numbered, 8.5x11-inch pages of single-spaced standard 12-point type with 1-inch margins. This is in addition to the 15 pages permitted for the Project Description. The Quality Assurance Narrative Statement should, for each item listed below, either present the required information or provide a justification as to why the item does not apply to the proposed research. For awards that involve environmentally related measurements or data generation, a quality system that complies with the requirements of ANSI/ASQC E4, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs," must be in place.

1. The activities to be performed or hypothesis to be tested (reference may be made to the specific page and paragraph number in the application where this information may be found); criteria for determining the acceptability of data quality in terms of precision, accuracy, representativeness, completeness, comparability.

2. The study design including sample type and location requirements and any statistical analyses that were used to estimate the types and numbers of samples required for physical samples or similar information for studies using survey and interview techniques.

3. The procedures for the handling and custody of samples, including sample identification, preservation, transportation, and storage.

4. The methods that will be used to analyze samples or data col-

lected, including a description of the sampling and/or analytical instruments required.

5. The procedures that will be used in the calibration and performance evaluation of the sampling and analytical methods used during the project.

6. The procedures for data reduction and reporting, including a description of statistical analyses to be used and of any computer models to be designed or utilized with associated verification and validation techniques.

7. The intended use of the data as they relate to the study objectives or hypotheses.

8. The quantitative and or qualitative procedures that will be used to evaluate the success of the project.

9. Any plans for peer or other reviews of the study design or analytical methods prior to data collection.

ANSI/ASQC E4, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs" is available for purchase from the American Society for Quality Control, phone 1-800-248-1946, item T55. Only in exceptional circumstances should it be necessary to consult this document.

J. Postcard: The Applicant must include with the application a self-addressed, stamped 3x5-inch post card. This will be used to acknowledge receipt of the application and to transmit other important information to the applicant.

How to Apply

The application and peer review processes will be managed by EPA for the cooperating agencies. The original and ten (10) copies of the fully developed application and five (5) additional copies of the abstract (15 in all), must be received by EPA **no later than 4:00 P.M. EDT on the closing date, September 16, 1998.**

The application and abstract must be prepared in accordance with these instructions. Informal, incomplete, or unsigned proposals will not be considered. The application should not be bound or stapled in any way. The original and copies of the application should be secured with paper or binder clips. Completed applications should be sent via regular mail to:

U.S. Environmental Protection Agency
Peer Review Division (8703R)
Sorting Code: 99-NCERQA-D1
or 99-NCERQA-D2
401 M Street, SW
Washington DC 20460

For express mail or courier-delivered applications, the following address must be used:

U.S. Environmental Protection Agency
Peer Review Division (8703R)
Sorting Code: 99-NCERQA-D1
or 99-NCERQA-D2
1300 Pennsylvania Avenue, NW
Room B-10105
Washington, DC 20004

Phone: (202) 564-6939 (for express mail applications)

Guidelines, Limitations, and Additional Requirements

If you wish to submit more than one application, you must ensure that the research proposed is significantly different from that in any other that you have submitted to this solicitation or from any other grant you are currently receiving from any federal government agency.

Projects that contain subcontracts constituting more than 40% of the total direct cost of the grant for each year in which the subcontract is awarded will be subject to special review and may require additional justification.

The NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) requires that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The policy contains some provisions that are substantially different from the 1990 policies. Grantees, regardless of funding source, will be expected to adhere to this policy.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which were published in the Federal Register of March 28, 1994 (FR 59, 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994. Investi-

gators also may obtain copies of the policy from the NIH program staff listed under **CONTACTS**. Program staff may also provide further discussion concerning the policy. Compliance with the above policies will be evaluated during the review process.

This program is described in the Catalog of Federal Domestic Assistance No. 93.113, 93.114, and 93.115. NIEHS awards are made under authorization of the Public Health Service Act, Title IV, Part a (Public Law 78-410, as amended by Public Law 99-158, 43 USC 241 and 285) and administered under PHS Grants Policies and Federal Regulations 42 CFR 52 and 45 CFR 74. EPA awards are made under authority of 40 CFR 30 and 40. This program is not subject to the intergovernmental review requirements of executive order 12372 or Health Systems Agency Review.

The sponsoring agencies strongly encourage all grant and contract recipients to provide a smoke free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children.

Researchers will be expected to budget for and participate in an annual All-Investigators Meeting with federal agency scientists and other grantees to report on research activities and to discuss issues of mutual interest.

Review and Selection

All grant applications are initially reviewed to determine their legal and administrative acceptability. Acceptable applications are then reviewed by an appropriate technical peer review group. This review is designed to evaluate each proposal according to its scientific merit. In general, the review group will be composed of scientists and engineers who are experts in their respective disciplines and are proficient in the technical areas they are reviewing. The reviewers use the following criteria to help them in their reviews:

1. The originality and creativity of the proposed research, the appropriateness and adequacy of the research methods proposed, and the appropriateness and adequacy of the Quality Assurance Narrative Statement. Is the research approach practical and technically defensible, and can the project be performed within the proposed time period? Will the research contribute to scientific knowledge in the topic area of the solicitation? Is the proposal well-prepared with supportive information that is self-explanatory and understandable?
2. The qualifications of the principal investigator and other key personnel, including research training, demonstrated knowledge of pertinent literature, experience, and publication records. Will all key personnel contribute a significant time commitment to the project?
3. The scientific environment, including the availability and/or adequacy of the facilities and equipment proposed for the project. Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

4. The responsiveness of the proposal to the research needs identified for the topic area. Does the proposal adequately address the objectives specified for this topic area?

5. Although budget information is not used by the reviewers as the basis for their evaluation of scientific merit, the reviewers are asked to provide their view on the appropriateness and/or adequacy of the proposed budget and its implications for the potential success of the proposed research. Input on requested equipment is of particular interest.

6. For projects involving human subjects, the adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for recruitment and retention of subjects will also be evaluated.

Applications that are of sufficient scientific quality based on the peer review are subjected to a programmatic review within each participating federal agency, the object being to assure a balanced research portfolio under this program. Scientists from the participating agencies review these applications in relation to program priorities and their complementarity to the ongoing research within each federal agency. Applications that are within the program areas of NIEHS will be reviewed by the National Advisory Environmental Health Sciences Council in accordance with PHS policy. Funding recommendations are developed by each participating federal agency.

Funding decisions are coordinated through the EDWG, with the final funding decision being the sole responsibility of the funding agency. Grants are selected on the basis of technical merit, relevancy to the

research priorities outlined, program balance, and budget. A summary statement of the scientific review by the peer panel will be provided to each applicant.

Applications selected for funding will require additional certifications, possibly a revised budget, and responses to any comments or suggestions offered by the peer reviewers. Project officers from each of the funding agencies will contact principal investigators to obtain these materials.

Proprietary Information

By submitting an application in response to this solicitation, the applicant grants EPA and other participating agencies permission to share the application with technical reviewers both within and outside of their respective organizations. Applications containing proprietary or other types of confidential information will be returned to the applicant without review.

Funding Mechanism

The funding mechanism for all awards issued under this solicitation will consist of grants from the federal agencies involved in this announcement and depends on the availability of funds. In accordance with Public Law 95-224, the primary purpose of a grant is to accomplish a public purpose of support or stimulation authorized by Federal statute rather than acquisition for the direct benefit of the government. Policies that govern grant award programs of each agency will prevail for respective sources of support. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

Contacts

Additional general information on the grants program, forms used for applications, etc., may be obtained by exploring the Web at

<<http://www.epa.gov/ncerqa>>.

The participating agencies do not intend to make mass-mailings of this announcement. Information may also be obtained by contacting:

**U.S. Environmental Protection Agency
National Center for Environmental Research and Quality Assurance (8703R)
401 M Street, SW
Washington DC 20460**

Phone: 1-800-490-9194

In addition, a contact person has been identified from each participating Agency or Department for additional information on this topic. These individuals will usually be either the Program Manager or the Project Officers for the grants funded under this announcement. They will respond to inquiries regarding the solicitation and can respond to any technical questions related to your application

Endocrine Disruptors

EPA Contacts

- **David Reese**
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NIEHS Contacts

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DOI Contact

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NOAA Contact

- **Teri Rowles**
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APPLICATION FOR FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION <i>Application</i> <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		<i>Preapplication</i> <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		2. DATE SUBMITTED	Applicant Identifier	
				3. DATE RECEIVED BY STATE	State Applicant Identifier	
				4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier	
5. APPLICANT INFORMATION IS THIS PROPOSAL BEING SUBMITTED TO ANOTHER FEDERAL AGENCY? <input type="checkbox"/> YES <input type="checkbox"/> NO IF YES, LIST ACRONYM(S)						
Legal Name:				Organizational Unit:		
Address (give city, county, state, and zip code):				Name and telephone and E-mail number of the person to be contacted on matters involving this application (give area code) PI: ADMIN. CONTACT:		
6. EMPLOYER IDENTIFICATION NUMBER (EIN): <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px 0;"></div>				7. TYPE OF APPLICANT: (enter appropriate letter in box) <div style="border: 1px solid black; width: 30px; height: 20px; display: inline-block;"></div>		
8. TYPE OF APPLICATION: <input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es): <div style="display: inline-block; width: 20px; height: 20px; border: 1px solid black; margin: 0 5px;"></div> <div style="display: inline-block; width: 20px; height: 20px; border: 1px solid black; margin: 0 5px;"></div> A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration Other (specify): _____				A. State H. Independent School Dist. B. County I. State Controlled Institution of Higher Learning C. Municipal J. Private University D. Township K. Indian Tribe E. Interstate L. Individual F. Intermunicipal M. Profit Organization G. Special District N. Other (Specify) _____		
				9. NAME OF FEDERAL AGENCY: U.S. Environmental Protection Agency - ORD - NCERQA		
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: <div style="display: flex; align-items: center; gap: 5px;"><div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">6</div><div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">6</div><div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">•</div><div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">5</div><div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">0</div><div style="border: 1px solid black; width: 20px; height: 20px; text-align: center;">0</div></div> TITLE: 99-NCERQA - _ _ _				11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:		
12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):						
13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICTS OF:				
Start Date	Ending Date	a. Applicant			b. Project	
15. ESTIMATED TOTAL PROJECT FUNDING:		16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?				
a. Federal	\$.00	a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE _____				
b. Applicant	\$.00					
c. State	\$.00	b. NO. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372 <input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW				
d. Local	\$.00					
e. Other	\$.00	17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT? <input type="checkbox"/> Yes If "Yes," attach an explanation. <input type="checkbox"/> No				
f. Program Income	\$.00					
g. TOTAL	\$.00					
18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.						
a. Typed Name of Authorized Representative			b. Title		c. Telephone number	
d. Signature of Authorized Representative					e. Date Signed	

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal Assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

- | Item: | Entry: | Item: | Entry: |
|-------|--|-------|---|
| 1. | Self-explanatory. | 12. | List only the largest political entities affected (e.g., State, counties, cities.) |
| 2. | Date application submitted to Federal agency (or State, if applicable) & applicant's control number (if applicable). | 13. | Self-explanatory. |
| 3. | State use only (if applicable). | 14. | List the applicant's Congressional Districts and any District(s) affected by the program or project. |
| 4. | If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank. | 15. | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, include <u>only</u> the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 5. | Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application. | 16. | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. |
| 6. | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service. | 17. | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit allowances, loans and taxes. |
| 7. | Enter the appropriate letter in the space provided. | 18. | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.) |
| 8. | Check appropriate box and enter appropriate letter(s) in the space(s) provided:

— "New" means a new assistance award.

— "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.

— "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. | | |
| 9. | Name of Federal agency from which assistance is being requested with this application. | | |
| 10. | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is required. | | |
| 11. | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project. | | |

KEY CONTACTS FORM

- ☐ **Authorized Representative:** *Original awards and amendments will be sent to this individual for review and acceptance, unless otherwise indicated.*

Name: _____

Title: _____

Complete Address: _____

Phone Number: _____

- ☐ **Payee:** *Individual authorized to accept payments.*

Name: _____

Title: _____

Complete Address: _____

Phone Number: _____

- ☐ **Administrative Contact:** *Individual from Sponsored Programs Office to contact concerning administrative matters (i.e., indirect cost rate computation, rebudgeting requests etc.)*

Name: _____

Title: _____

Complete Address: _____

Phone Number: _____

FAX Number: _____

E-Mail Number: _____

- ☐ **Principal Investigator:** *Individual responsible for the technical completion of the proposed work.*

Name: _____

Title: _____

Complete Address: _____

Phone Number: _____

FAX Number: _____

E-Mail Number: _____

EPA STAR Grant Abstract (*Example Format*)

Sorting Code: 99-NCERQA-XX (*use the correct code that corresponds to the appropriate RFA topic*)

Title: *Use the exact title as it appears in the rest of the application.*

Investigators: *List the names and affiliations of each investigator who will significantly contribute to the project. Start with the Principal Investigator.*

Institution: *Name of university or other applicant.*

Project Period: *October 1, 1999--September 30, 2001, for example.*

Research Category: *Enter your research topic name.*

Project Summary:

Objectives/Hypothesis: *include a short statement on the context of the proposed research in relation to other environmental research in the particular area of work*

Approach: *outline the methods, approaches, and techniques you intend to employ in meeting the objectives*

Expected Results:

including a brief description of the

Improvements in Risk Assessment or Risk Management

that will be realized if the expected results are achieved

Supplemental Keywords: *see attached suggestions. Do not duplicate terms used in the text of the abstract.*

SUGGESTED KEYWORDS

Media: (media, air, ambient air, atmosphere, ozone, water, drinking water, watersheds, groundwater, land, soil, sediments, acid deposition, global climate, indoor air, mobile sources, CASTNET, stratospheric ozone, tropospheric, marine, estuary, precipitation, leachate, adsorption, absorption, chemical transport)

Risk Assessment: (exposure, risk, risk assessment, effects, health effects, ecological effects, human health, bioavailability, metabolism, vulnerability, sensitive populations, dose-response, carcinogen, teratogen, mutagen, animal, mammalian, organism, cellular, population, enzymes, infants, children, elderly, stressor, age, race, diet, metabolism, genetic pre-disposition, genetic polymorphisms, sex, ethnic groups, susceptibility, cumulative effects)

Chemicals, toxics, toxic substances: (chemicals, toxics, particulates, ODS, VOC, CFC, PAH, PNA, PCB, dioxin, metals, heavy metals, solvents, oxidants, nitrogen oxides, sulfates, organics, DNAPL, NAPL, pathogens, viruses, bacteria, acid rain, effluent, discharge, dissolved solids, intermediates)

Ecosystem Protection: (ecosystem, indicators, restoration, regionalization, scaling, terrestrial, aquatic, habitat, integrated assessment)

Risk Management: pollution prevention (green chemistry, life-cycle analysis, alternatives, sustainable development, clean technologies, innovative technology, renewable, waste reduction, waste minimization, environmentally conscious manufacturing); treatment (remediation, bioremediation, cleanup, incineration, disinfection, oxidation, restoration)

Public Policy: (public policy, decision making, community-based, cost-benefit, conjoint analysis, observation, non-market valuation, contingent valuation, survey, psychological, preferences, public good, Bayesian, socio-economic, willingness-to-pay, compensation, conservation, environmental assets, sociological)

Scientific Disciplines: (environmental chemistry, marine science, biology, physics, engineering, social science, ecology, hydrology, geology, histology, epidemiology, genetics, pathology, mathematics, limnology, entomology, zoology)

Methods/Techniques: (EMAP, modeling, monitoring, analytical, surveys, measurement methods, general circulation models, climate models, satellite, landsat, remote sensing)

Geographic Areas: (Northeast, central, Northwest, Chesapeake Bay, Great Lakes, Midwest, Mid-Atlantic, states: {use both full name and two letter abbreviation}, EPA Regions 1 through 10)

Sectors: (agriculture, business, transportation, industry {petroleum, electronics, printing, etc}): {identify 4 digit SIC codes}, service industry, food processing, etc)

Current and Pending Support

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.

Investigator:	Other agencies (including NSF) to which this proposal has been/will be submitted.
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Support:	<input type="checkbox"/> Current	<input type="checkbox"/> Pending	<input type="checkbox"/> Submission Planned in Near Future	<input type="checkbox"/> Transfer of Support
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Project/Proposal Title:

Source of Support:

Total Award Amount: \$ _____ Total Award Period Covered: _____

Location of Project: _____

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support:	<input type="checkbox"/> Current	<input type="checkbox"/> Pending	<input type="checkbox"/> Submission Planned in Near Future	<input type="checkbox"/> Transfer of Support
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Project/Proposal Title:

Source of Support:

Total Award Amount: \$ _____ Total Award Period Covered: _____

Location of Project: _____

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support:	<input type="checkbox"/> Current	<input type="checkbox"/> Pending	<input type="checkbox"/> Submission Planned in Near Future	<input type="checkbox"/> Transfer of Support
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Project/Proposal Title:

Source of Support:

Total Award Amount: \$ _____ Total Award Period Covered: _____

Location of Project: _____

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

Support:	<input type="checkbox"/> Current	<input type="checkbox"/> Pending	<input type="checkbox"/> Submission Planned in Near Future	<input type="checkbox"/> Transfer of Support
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Project/Proposal Title:

Source of Support:

Total Award Amount: \$ _____ Total Award Period Covered: _____

Location of Project: _____

Person-Months Per Year Committed to the Project. Cal: Acad: Sumr:

*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

Itemized Budget for EPA STAR Grant Applications (*Example Format*)

CATEGORIES	YEAR ONE	YEAR TWO	YEAR THREE	TOTAL PROJECT
a. Personnel Principal Investigator Co-PI Research Scientists Postdoctoral Scientists Other Personnel				
TOTAL PERSONNEL COSTS				
b. Fringe Benefits _____ % of _____				
c. Travel Trip 1 Trip 1 Trip 1 ...etc.				
TOTAL TRAVEL COSTS				
d. Equipment Item 1 Item 2 Item 3 ...etc.				
TOTAL EQUIPMENT COSTS				
e. Supplies Item 1 Item 2 Item 3 ...etc.				
TOTAL SUPPLY COSTS				
f. Contracts 1 2 3 ...etc.				
TOTAL CONTRACTUAL COSTS				
g. Other Item 1 Item 2 Item 3 ...etc.				
TOTAL OTHER COSTS				
h. TOTAL DIRECT COSTS (sum of a-g)				
i. Indirect Costs/Charges _____ % of _____ (base)				
j. TOTAL PROJECT COSTS (sum of h & i)				
k. TOTAL REQUESTED FROM EPA				